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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,094	DODGSON, KIRSTY JANE	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 44-55* is/are pending in the application.

4a) Of the above claim(s) *2-7,10-14,20-22,24 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8,9, 1519, 23, 25 and 44-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Amendment Entry

2. The amendment filed October 31, 2007 has been entered. Claim 1 has been amended. Claims 2-7, 10-14, 20-22, 24 and 26-43 have been withdrawn from consideration. Claims 50-55 have been newly added. Claims 1, 8-9, 15-19, 23, 25 and 44-55 are under consideration in this office action.

Response to Arguments

3. Applicant's arguments filed October 31, 2007 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The written description rejection of claims 1, 8-9, 15-19, 23, 25 and 44-55 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record. The rejection is on the grounds that the specification teaches the structure of only a single representative species of SEQ ID NO:2, 3 and 4. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of hybridizing to SEQ ID NO:2, 3 or 4. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention. With respect to claims 1, 8, 9 and 46-49, there is no description of polypeptides having at least 80%, 85%, 90%, 95% or 97% sequence identity to SEQ ID NO:2, 3 or 4. Also there is no support for the primers or probe consisting of 15 to 40 nucleotides which include SEQ DI NO:2, 3 or 4.

The claims are drawn to a method to detect *vanA* in a sample, comprising: a) contacting a sample suspected of comprising amplified *vanA* nucleic acid with at least one *vanA*-specific oligonucleotide probe under conditions effective to form a hybrid between the *vanA*-specific oligonucleotide probe and *vanA* nucleic acid in the sample, wherein the *vanA*-specific oligonucleotide probe has 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3, wherein the amplified *vanA* nucleic acid is obtained with two oligonucleotide primers having 15 to 40 nucleotides, wherein a first oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:2, and a second oligonucleotide

primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4, wherein the probe is one which under the same conditions hybridizes to SEQ ID NO:3 or its complement, wherein the first primer hybridizes to the complement of SEQ ID NO:2, and wherein the second primer hybridizes to the complement of SEQ ID NO:4; and b) detecting or determining the presence or amount of hybrid formation, wherein hybrid formation is indicative of *vanA* nucleic acid in the sample. The claims are also drawn to the primers or probe consisting of 15 to 40 nucleotides which include SEQ ID NO:2, 3 or 4.

Applicants assert that the recited vanA-specific probes and primers have a common structure and function. The specification does not place any structure, chemical functional limitations on the polynucleotide probe per se. The recitation of primers hybridizing does not convey a common structure or function. No information, beyond the characterization of a probes having SEQ ID NO:3 and primers having SEQ ID NO:2 and 4 have been provided, which would indicate that applicants had possession of the claimed genus of any probes and primers that are about 15 to 40 nucleotides with at least 80% sequence identity to SEQ ID NO:2, 3 or 4. The specification does not contain any disclosure of the structure of variants falling within the scope of the claimed genus. The genus of the probes and primers claimed is a large variable genus including mutants and variants, which can have wide variety of structures. The specification discloses the structure of only a single representative species of the claimed genus i.e. SEQ ID NO: 2, 3 and 4 which is insufficient to put one

of skill in the art in possession of the attributes and features of all species within the claimed genus.

The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the primers. Structural features that could distinguish molecules in the genus from others in the class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. The specification and claims lack sufficient written description of the generically claimed hybridizing primers which is defined by its function, i.e., hybridizing. While the description of the ability of the claimed primers to hybridize, may describe the primer's function, it does not describe the primers themselves. The hybridization distinctions are purely functional distinctions which are insufficient.

Applicants' assert that one of skill in the art can clearly envision variants of SEQ ID NO:2-4 with a specific percent sequence identity thereto. However, while it is noted that the claims recite SEQ ID NO:2, 3 and 4 the skilled artisan cannot envision the detailed structure of the sequences having at least 80%, 85%, 90% or 95% sequence identity since the specification has failed to define what nucleotides are essential for their performance in the method of detection. Therefore, there is no description of any oligonucleotides having the instantly recited characteristics. The claims fail to recite

what the probes or primers having 40 nucleotides are. In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of the claimed probes and primers.

Since the disclosure fails to describe the common attributes or structural characteristics that identify the members of the genus, and because the genus of nucleic acid molecules of is highly variable, the function of hybridization alone is insufficient to describe the genus of nucleic acid molecules. The specification teaches the structure of only a single representative species of SEQ ID NO:2, 3 and 4. There is no description of polypeptides having at least 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:2, 3 or 4. There is no description of oligonucleotides having 15 to 40 nucleotides with at least 80% sequence identity to SEQ ID NO:2, 3 or 4 fail to meet the written description provision of 35 UCS 112, first paragraph. SEQ ID NO:2 has 18 amino acids, SEQ ID NO:3 has 27 amino acids and SEQ ID NO:4 has 20 amino acids. There is no description of probes and primers having 15 to 40 nucleotides, when SEQ ID NO:2, 3 and 4 do not have 40 nucleotides. There is no description of what the additional nucleotides are. There is no description of a probe or primer that has at least 80% sequence identity to a sequence with additional unknown nucleotides. The specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being capable of hybridizing to SEQ ID NO:2, 3 or 4.

Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The new matter rejection of claims 1, 8-9, 15-19, 23, 25 and 44-55 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The rejection is on the grounds that neither the specification nor originally presented claims provides support for a method to detect *vanA* in a sample, comprising: a) contacting a sample suspected of comprising amplified *vanA* nucleic acid with at least one *vanA*-specific oligonucleotide probe under conditions effective to form a hybrid between the *vanA*-specific oligonucleotide probe and *vanA* nucleic acid in the sample, wherein the *vanA*-specific oligonucleotide probe has 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3, wherein the amplified *vanA* nucleic acid is obtained with two oligonucleotide primers having 15 to 40 nucleotides, wherein a first oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4, wherein the probe is one which under the same conditions hybridizes to SEQ ID NO:3 or its complement, wherein the first primer hybridizes to the complement of SEQ ID NO:2, and wherein the second primer is hybridizes to the complement of SEQ ID NO:4; and b)

detecting or determining the presence or amount of hybrid formation, wherein hybrid formation is indicative of *vanA* nucleic acid in the sample.

Applicants point to the definition of probes and primers at page 13 and a statement that oligonucleotides having lengths from 15 to 40 nucleotides are homologous to the target nucleic acids to permit amplification (see page 19). However, Applicant did not point to support in the specification for at least one vanA-specific oligonucleotide wherein the *vanA*-specific oligonucleotide probe having 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3 and hybridizes to SEQ ID NO:3. Applicant has not disclosed what the additional 13 nucleotides are in order to have a probe that has 40 nucleotides. Neither pages 19 or 20 of the instant specification disclose such information. Furthermore, the specification at pages 13, 19, and 20 states oligonucleotides probes of different lengths and base composition may be used for detecting the *vanA* gene or the *vanB* gene, preferred oligonucleotides have lengths from 15 up to 40 nucleotides and are sufficiently homologous to the target nucleic acid to permit amplification of a *vanA* or *vanB* template and/or hybridization to such a template under high stringency conditions. However the specification fails to discloses probes and primers probe has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:2, 3 or 4 or the complement of SEQ ID NO:2, 3 or 4 that hybridizes to SEQ ID NO:2, 3 or 4.

There is no teaching of a first oligonucleotide primer that has at least 80% nucleic acid sequence identity to SEQ ID NO:2, wherein the first primer hybridizes to the

complement of SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4 and wherein the second primer hybridizes to the complement of SEQ ID NO:4. With respect to claims 50-53, there is no teaching of a primer that consists of 15 to 40 nucleotides which include SEQ ID NO:2, 3, or 4. Thus, there appears to be no teaching of the *vanA* specific oligonucleotide probe that has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3 that hybridizes to SEQ ID NO:3; a first oligonucleotide primer that has at least 80% nucleic acid sequence identity to SEQ ID NO:2, wherein the first primer hybridizes to the complement of SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4 and wherein the second primer hybridizes to the complement of SEQ ID NO:4. Thus it appears that the entire specification appears to fail to recite support for the *vanA* specific oligonucleotide probe and oligonucleotide primers. Accordingly, the rejection is maintained and applicants' arguments are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The rejection of claims 1, 8-9, 15-19, 23,25 and 44-55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

a) Claims 1 and 50-53 are unclear. The amendment to claim 1 does not overcome the rejection. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, the claims are drawn to a *vanA-specific* oligonucleotide probe that has 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3; two oligonucleotide primers having 15 to 40 nucleotides, wherein a first oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:2; and a second oligonucleotide primer has at least 80% nucleic acid sequence identity SEQ ID NO:4.

SEQ ID NO:2 has 18 amino acids, SEQ ID NO:3 has 27 amino acids and SEQ ID NO:4 has 20 amino acids. The language of the claim does not clarify the claim. It is unclear how applicants are defining the probes and primers. Claims 1 and 50-53 recite

the broad limitation of having 15 to 40 nucleotides, yet SEQ ID NO:2, 3 and 4 do not have 40 nucleotides, the sequences have 18, 27 and 20 nucleotides respectively. This is the narrower statement of the range/limitation. The claims and specification fail to disclose what the other nucleotides are. Thus the metes and bounds of the claim cannot be ascertained by one of ordinary skill in the art and clarification is required to overcome the rejection.

b) The term " hybridizes" in the claim is a relative term which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification teaches that stringent conditions are sequence-dependant and will be different in different circumstances. As such, the hybridization is dependant upon specific conditions that are not recited in the claims and specification fails to define the metes and bounds of the hybridization conditions. Therefore one skilled in the art would not be readily apprised as to the metes and bounds of the hybridizing probes or primers. Therefore, clarification is required to overcome the rejection.

The specification at pages 21-22 teaches specific conditions such as having a PCR reaction mixtures containing 50mM KCl, 10mM Tris-HCl pH 8.3, 2.5 mM MgC12, 0.4/zm of each of the two primers, 200 uM of each of the four dNTPs and 1.25 Units of Taq DNA polymerase (Perkin Elmer). PCR reactions are then subjected to thermal cycling (3 minutes at 95°C followed by 30 cycles of 1 second at 95°C and 1 second at 55°C) using a Perkin Elmer 480 ™ thermal cycle and subsequently analyzed by

standard ethidium bromide-stained agarose gel electrophoresis. As such, the action of hybridizing is dependant upon specific conditions that are not recited in the claims and specification fails to define the metes and bounds of the phrase. Therefore one skilled in the would not be readily apprised as to the metes and bounds of the hybridizing probes or primers. Therefore, clarification is required to overcome the rejection.

c) The phrase "one which under the same conditions hybridizes" in claim 1 is a relative term which renders the claim indefinite. The term "one which under the same conditions hybridizes" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what "the same conditions" are since no conditions have been recited. It is unclear what the "same conditions" are. Therefore the metes and bounds of the phrase are unclear and clarification is required to overcome the rejection.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 24, 2008

MARK NAVARRO
PRIMARY EXAMINER